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TO:

Name: Mail Stop Appeal Brief--Patents
Art Unit 3764/Examiner D. DeMille

Firm: U.S. Patent & Trademark Office

Fax No.: 703-872-9306

Subject: U.S. Patent Application No. 08/354,450
Gary K. Michelson
Filed: December 12, 1994
DEVICE FOR ARTHROSCOPIC MENISCAL REPAIR
Attorney Docket No. 101.0023-04000
Customer No. 22882
Confirmation No.: 3041

FROM:

Name: Todd M. Martin

Phone No.: 310-286-9800

No. of Pages (including this): 80

Date: April 20, 2005

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PATENT
Attorney Docket No. 101.0023-04000
Customer No. 22882

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:
Gary K. Michelson
Serial No: 08/354,450
Filed: December 12, 1994
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Confirmation No.: 3041

Art Unit: 3764
Examiner: D. DeMille

Mail Stop Appeal Brief--Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Transmitted herewith is an Appeal Brief in the above-identified application.

- ☒ Applicant claims small entity status under 37 C.F.R. §§ 1.9 and 1.27.
- ☐ No additional fee is required.
- ☒ Applicant hereby requests a five-month extension of time to further respond to the Notice of Appeal filed September 20, 2004.
- ☒ The total amount of $1,330.00 (to cover the $1,080 five-month extension of time fee and $250 Appeal Brief fee) is to be charged to Deposit Account No. 50-1066.
- ☒ The Commissioner is hereby authorized to charge any deficiencies of fees associated with this communication or credit any overpayment to Deposit Account No. 50-1066. **A copy of this sheet is enclosed.**
  - ☒ Any filing fees under 37 C.F.R. § 1.16 for the presentation of extra claims
  - ☒ Any patent application processing fees under 37 C.F.R. § 1.17

Respectfully submitted,
MARTIN & FERRARO, LLP

Date: April 20, 2005

By: Todd M. Martin
Todd M. Martin
Registration No. 42,844

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PATENT
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PATENT
Attorney Docket No. 101.0023-04000
Customer No. 22882

APPEAL TO THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:	)	
Gary Karlin Michelson, M.D.	)	
Serial No.: 08/354,450	)	Group Art Unit: 3764
Filed: December 12, 1994	)	Examiner: D. DeMille
For: DEVICE FOR ARTHROSCOPIC MENISCAL REPAIR	)	

Mail Stop APPEAL BRIEF-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

APPEAL BRIEF

Real Party in Interest

The real party in interest is Gary Karlin Michelson, M.D. (hereinafter, the "Appellant").

Related Appeals and Interferences

There are no appeals or interferences pending which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

Status of Claims

Claims 1-28 have been cancelled.

Claims 29-300 are pending.

Claims 29-300 have been rejected and are being appealed.

Status of Amendments

An amendment under 37 C.F.R. § 1.116 dated September 20, 2004 (the "September 2004 Amendment") was entered by the Examiner in the Advisory Action dated November 4, 2004 (the "November 2004 Advisory Action").

Summary of Claimed Subject Matter

Independent claim 29.

The present invention in one preferred embodiment is directed to a tissue rivet 100 (Specification, page 7, lines 1 and 2; Fig. 5) for holding pieces of tissue M (Specification, page 6, lines 7-19; Fig. 4) together and preventing movement of rivet 100 in the tissue. Rivet 100 is made of a bioabsorbable material (Specification, page 6, lines 27-31), and comprises a shaft 112 (Specification, page 7, lines 6-8; Fig. 5) having a leading end (Fig. 5), a trailing end 120 (Fig. 5) opposite the leading end, and a mid-longitudinal axis (Specification, page 7, line 7) therebetween. Shaft 112 has a maximum cross-sectional dimension transverse to the mid-longitudinal axis (Fig. 5), a truncated conical penetration head 114 (Specification, page 7, lines 1 and 2; Fig. 5) at the leading end, and a flexible member 118 (Specification, page 7, line 6; Fig. 5) at trailing end 120. Flexible member 118 has a top (Fig. 8), a bottom (Fig. 5) opposite the top, and a dimension larger than the maximum cross-sectional dimension of shaft 112. Flexible member 118 is adapted to deform so as to conform to the surface of the tissue in which the rivet is inserted. (Specification, page 6, lines 31-33). Flexible member 118 is at least in part curved when flexible member 118 is in contact with the tissue M (Fig. 2; the meniscus is curved (see Exhibit A), thus the flexible member is curved when in contact with the tissue of the meniscus). Shaft 112 has a plurality of flexible projections 116 (Specification, page 7, lines 2-5; Fig. 5) extending radially from shaft 112. Flexible projections 116 are separate and spaced apart from one another (Fig. 5). At least one of flexible projections 116 is capable of flexing (Specification, page 6, line 27) toward shaft 112 when being inserted in the tissue (Fig. 7).

Independent claim 60.

The present invention in another preferred embodiment is directed to a tissue rivet 100 (Specification, page 7, lines 1 and 2; Fig. 5) for holding pieces of tissue M (Specification, page 6, lines 7-19; Fig. 4) together. Rivet 100 is made of a bioabsorbable material (Specification, page 6, lines 27-31), and comprises a shaft 112 (Specification, page 7, lines 6-8; Fig. 5) having a leading end (Fig. 5), a trailing end 120 (Fig. 5) opposite the leading end, and a mid-longitudinal axis (Specification, page 7, line 7) therebetween. Shaft 112 has a maximum cross-sectional dimension transverse to

the mid-longitudinal axis (Fig. 5), is at least in part conical at the leading end and has a flexible member 118 (Specification, page 7, line 6; Fig. 5) at trailing end 120. Flexible member 118 has a top (Fig. 8), a bottom (Fig. 5) opposite the top, and a dimension larger than the maximum cross-sectional dimension of shaft 112. Flexible member 118 is adapted to deform so as to conform to the surface of the tissue in which the rivet is inserted. (Specification, page 6, lines 31-33). The top of flexible member 118 is at least in part concave when flexible member 118 is in contact with the tissue M (Fig. 2; the meniscus is concave (see Exhibit A), thus the top of the flexible member will be concave when in contact with the tissue of the meniscus). Shaft 112 has a plurality of flexible projections 116 (Specification, page 7, lines 2-5; Fig. 5) extending radially from shaft 112. Flexible projections 116 are separate and spaced apart from one another (Fig. 5).

Independent claim 100.

The present invention in another preferred embodiment is directed to a tissue rivet 100 (Specification, page 7, lines 1 and 2; Fig. 5) for holding pieces of tissue M (Specification, page 6, lines 7-19; Fig. 4) together. Rivet 100 comprises a shaft 112 having a leading end (Fig. 5), a trailing end 120 (Fig. 5) opposite the leading end, and a mid-longitudinal axis (Specification, page 7, line 7) therebetween. Shaft 112 has an exterior surface with at least one projection 116 adapted to resist expulsion of rivet 100 from within the tissue. (Specification, page 3, lines 23-25). Rivet 100 includes a flexible member 118 proximate trailing end 120 of shaft 112. Flexible member 118 has a top (Fig. 8) and a bottom (Fig. 5) opposite the top, the bottom adapted to contact tissue upon insertion of rivet 100 into the tissue (Fig. 7). Flexible member 118 is at least in part curved when the bottom of flexible member 118 contacts the tissue. (Fig. 2; the meniscus is curved (see Exhibit A), thus the flexible member will be curved when in contact with the tissue of the meniscus).

Independent claim 144.

The present invention in another preferred embodiment is directed to a tissue rivet 100 (Specification, page 7, lines 1 and 2; Fig. 5) for holding pieces of tissue M (Specification, page 6, lines 7-19; Fig. 4) together. Rivet 100 comprises a shaft 112 having a leading end (Fig. 5), a trailing end 120 (Fig. 5) opposite the leading end, and a

mid-longitudinal axis (Specification, page 7, line 7) therebetween. Shaft 112 has an exterior surface with at least one projection 116 adapted to resist expulsion of rivet 100 from within the tissue. (Specification, page 3, lines 23-25). Rivet 100 includes a flexible member 118 proximate trailing end 120 of shaft 112. Flexible member 118 has a top (Fig. 8) and a bottom (Fig. 5) opposite the top, the bottom adapted to contact tissue upon insertion of rivet 100 into the tissue (Fig. 7). At least a portion of the bottom of flexible member 118 forms an included angle relative to the mid-longitudinal axis of shaft 112 that is greater than 90 degrees. (Fig. 7; see also Exhibit D, angle A).

Independent claim 176.

The present invention in another preferred embodiment is directed to a tissue rivet 100 (Specification, page 7, lines 1 and 2; Fig. 5) for holding pieces of tissue M (Specification, page 6, lines 7-19; Fig. 4) together. Rivet 100 comprises a shaft 112 having a leading end (Fig. 5) for insertion first into the tissue, a trailing end 120 (Fig. 5) opposite the leading end, and a mid-longitudinal axis (Specification, page 7, line 7) therebetween. Shaft 112 has an exterior surface with at least one projection 116 adapted to resist expulsion of rivet 100 from within the tissue. (Specification, page 3, lines 23-25). Rivet 100 includes a flexible member 118 proximate trailing end 120 of shaft 112. Flexible member 118 has a top (Fig. 8) and a bottom (Fig. 5) opposite the top that is adapted to contact tissue. (Fig. 7). Flexible member 118 has an outer perimeter between the top and the bottom (Fig. 5), at least a portion of the outer perimeter being flexible relative to shaft 112 when rivet 100 is inserted into the tissue. (Specification, page 6, lines 31-33; Figs. 6-7).

Independent claim 211.

The present invention in another preferred embodiment is directed to a tissue rivet 100 (Specification, page 7, lines 1 and 2; Fig. 5) for holding pieces of tissue M (Specification, page 6, lines 7-19; Fig. 4) together. Rivet 100 comprises a shaft 112 having a leading end (Fig. 5), a trailing end 120 (Fig. 5) opposite the leading end, and a mid-longitudinal axis (Specification, page 7, line 7) therebetween. Shaft 112 has an exterior surface with at least one projection 116 adapted to resist expulsion of rivet 100 from within the tissue. (Specification, page 3, lines 23-25). Rivet 100 includes a member 118 proximate trailing end 120 of shaft 112. Member 118 has a top (Fig. 8)

and a bottom (Fig. 5) opposite the top, and an outer perimeter, the bottom being adapted to contact tissue upon insertion of rivet 100 into the tissue (Fig. 7). At least a first portion of the bottom adjacent to the outer perimeter is at an acute angle relative to the mid-longitudinal axis of shaft 112 (Fig. 7; see also Exhibit D, angle A), at least a second portion of the bottom adjacent to the outer perimeter is at an obtuse angle relative to the mid-longitudinal axis of shaft 112 (Fig. 7; see also Exhibit D, angle B).

Independent claim 242.

The present invention in another preferred embodiment is directed to a tissue rivet 100 (Specification, page 7, lines 1 and 2; Fig. 5) for holding pieces of tissue M (Specification, page 6, lines 7-19; Fig. 4) together. Rivet 100 comprises a shaft 112 having a leading end (Fig. 5) for insertion first into the tissue, a trailing end 120 (Fig. 5) opposite the leading end, and a mid-longitudinal axis (Specification, page 7, line 7) therebetween. Shaft 112 has an exterior surface with at least one projection 116 adapted to resist expulsion of rivet 100 from within the tissue. (Specification, page 3, lines 23-25). Rivet 100 includes a member 118 proximate trailing end 120 of shaft 112. Member 118 has a top (Fig. 8) and a bottom (Fig. 5) opposite the top that is adapted to contact tissue. (Fig. 7). At least a portion of member 118 is moveable relative to shaft 112 between an undeployed position where the bottom surface is not in contact with the tissue (Fig. 6) and a deployed position where the bottom surface contacts the tissue (Fig. 7). Member 118 has a first shape in the deployed position and a second shape in the undeployed position, the first shape being different from the second shape. (Figs. 6-7).

Independent claim 273.

The present invention in another preferred embodiment is directed to a method for holding pieces of tissue M (Specification, page 6, lines 7-19; Fig. 4) together with a tissue rivet 100 (Specification, page 7, lines 1 and 2; Fig. 5). The method comprises the step of providing rivet 100 having a shaft 112 with a leading end (Fig. 5) for insertion first into the tissue, a trailing end 120 (Fig. 5) opposite the leading end, a mid-longitudinal axis (Specification, page 7, line 7) therebetween, and a member 118 proximate trailing end 120 of shaft 112. Member 118 has a top (Fig. 8), a bottom (Fig. 5) opposite the top, the bottom being adapted to contact tissue (Fig. 7). At least a

portion of member 118 is moveable relative to shaft 112 between an undeployed position where the bottom surface is not in contact with the tissue (Fig. 6) and a deployed position where the bottom surface contacts the tissue (Fig. 7), the member having a first shape in the deployed position (Fig. 6) and a second shape in the undeployed position (Fig. 7), the first shape being different from the second shape (Figs. 6-7). The method also includes the steps of inserting rivet 100 into the tissue until the bottom contacts the tissue (Specification, page 7, lines 27-29; Figs. 6-7); and moving at least a portion of the member relative to the shaft to the deployed position (Specification, page 7, lines 29-31; Fig. 7).

Independent claim 283.

The present invention in another preferred embodiment is directed to a method for holding pieces of tissue M (Specification, page 6, lines 7-19; Fig. 4) together with a tissue rivet 100 (Specification, page 7, lines 1 and 2; Fig. 5). The method comprises the step of providing rivet 100 having a shaft 112 with a leading end (Fig. 5) for insertion first into the tissue, a trailing end 120 (Fig. 5) opposite the leading end, and a flexible member 118 proximate trailing end 120 of shaft 112. Member 118 has a top (Fig. 8), a bottom (Fig. 5) opposite the top. The method also comprises the steps of engaging a driving instrument 130 to rivet 100 (Specification, page 7, lines 21-23; Figs. 5-6); and inserting rivet 100 into the tissue until the bottom of flexible member 118 contacts the tissue (Specification, page 7, lines 27-29) and flexible member 118 deforms to conform to the curvature of the tissue adjacent 100 rivet (Specification, page 7, lines 29-31; Figs. 6-7).

Independent claim 293.

The present invention in another preferred embodiment is directed to a method for holding pieces of tissue M (Specification, page 6, lines 7-19; Fig. 4) together with a tissue rivet 100 (Specification, page 7, lines 1 and 2; Fig. 5). The method comprises the step of providing rivet 100 having a shaft 112 with a leading end (Fig. 5) for insertion first into the tissue, a trailing end 120 (Fig. 5) opposite the leading end, and a member 118 proximate trailing end 120 of shaft 112. Member 118 has a top (Fig. 8), a bottom (Fig. 5) opposite the top, and an outer perimeter (Fig. 5). The method also includes the step of inserting rivet 100 into the tissue until the bottom of member 118 contacts the

tissue (Fig. 7). At least a first portion of the bottom adjacent to the outer perimeter of member 118 is at an acute angle relative to the mid-longitudinal axis of shaft 112 (Fig. 7; see also Exhibit D, angle A). At least a second portion of the bottom adjacent to the outer perimeter of member 118 is at an obtuse angle relative to the mid-longitudinal axis of shaft 112 (Fig. 7; see also Exhibit D, angle B).

Grounds of Rejection to be Reviewed on Appeal

I. The amendment filed January 7, 2004 (the "January 2004 Amendment") stands objected to under 35 U.S.C. § 132 for introducing new matter. In particular, the Examiner contends that the phrases listed below and recited in the claims are not supported by the original disclosure.

A. "[S]aid flexible member being at least in part curved" (corresponding to item (a) of the objection under 35 U.S.C. § 132 on page 2 of the Final Office Action dated March 19, 2004 (the "March 2004 Office Action").

B. "[S]aid flexible member is deformable to have an at least in part concave shape" (corresponding to item (b) of the March 2004 Office Action).

C. "[S]aid flexible member has a greater surface area to mass ratio than said shaft" (corresponding to item (c) of the March 2004 Office Action).

D. "[S]aid flexible member has a smaller mass than the mass of said shaft" (corresponding to item (d) of the March 2004 Office Action).

E. "[A]t least a second portion of said bottom of said flexible member forms an included angle relative to the mid-longitudinal axis of said shaft that is less than 90 degrees" (corresponding to item (i) of the March 2004 Office Action).

F. "[A]t least a first portion of said bottom adjacent to said outer perimeter being at an acute angle relative to the mid-longitudinal axis of said shaft" (corresponding to item (k) of the March 2004 Office Action).

G. "[A]t least a second portion of said bottom adjacent to said outer perimeter being at an obtuse angle relative to the mid-longitudinal axis" (corresponding to item (l) of the March 2004 Office Action).

II. The specification stands objected to under 35 U.S.C. § 112, first paragraph, as not providing support as originally filed for claims 29-300 (under Ground I, sub-grounds A to G, listed above).

III. Claims 29-300 stand rejected under 35 U.S.C. § 112, first paragraph, as not being adequately described by the specification (under Ground I, sub-grounds A to G, listed above).

IV. Claims 29-300 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.

V. Claims 29-37, 44-52, 60-69, 76-86, 95-111, 114, 115, 118-130, 139-153, 156, 159-167, 173-188, 191, 192, 194-202, 208-219, 222, 225-233, 239-250, 253, 256-264, 270-276, 278, 279, 282-285, 289, 292-294, 296, 297, and 300 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,261,914 to Warren ("Warren").

VI. Claims 29-37, 40, 41, 44-69, 72, 73, 76-86, 89-111, 114, 115, 118-130, 133-153, 156, 159-188, 191, 194-219, 222, 225-250, 253, and 256-300 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,976,715 to Bays et al. ("Bays") in view of Warren.

VII. Claims 38-43, 46-48, 70-75, 78-80, 112-117, 120-122, 154-161, 189-196, 220-227, 251-258 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Bays and Warren, and further in view of U.S. Patent No. 4,548,202 to Duncan ("Duncan"); U.S. Patent No. 4,728,238 to Chisholm et al. ("Chisholm") or U.S. Patent No. 4,422,276 to Paravano ("Paravano").

VIII. Claims 87, 88, 131, and 132 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Bays, Warren, Chisholm, Paravano, and Duncan, and further in view of U.S. Patent No. 4,338,835 to Simons ("Simmons").

Argument

The Appellant submits the following arguments for consideration by the Board of Patent Appeals and Interferences:

I. Objection to the amendment filed January 7, 2004 under 35 U.S.C. § 132.

A. The phrase "said flexible member being at least in part curved" applicable to independent claims 29 and 100.

Appellant discloses that the flexible member is flexible "so as to be able to conform to the angle of the meniscus M," and "deform so as to conform to the surface of the meniscus." (Specification, page 6, lines 31-33; and page 7, lines 30-31). It is well known to those skilled in the art of orthopedic surgery that the surface of the meniscus is curved. (See, e.g., Anatomy of the Human Body, Gray Henry, 20th ed., Fig. 349 (1918), a copy of which is attached hereto as Exhibit A). The surgeon installs the rivet of the present invention by inserting the shaft into the tissue of the torn meniscus. After the rivet is fully deployed, the shaft will have penetrated the portions of the meniscus tissue being repaired and the flexible member will be in contact with surface of meniscus. When the flexible member contacts the surface of the meniscus, due to the curvature of the meniscus, the forces between the underside of the flexible member and the tissue of the meniscus cause at least a portion of the perimeter of the flexible member to flex away from the shaft. As a result, at least a portion of the perimeter is elevated relative to the middle of the flexible member overlying the shaft, which is held in place by the shaft. This deformation of the flexible member forms a curve to conform to the curve of the top surface of the meniscus into which the flexible member is inserted. As a result of the deformation, the top surface of the flexible member can become curved to create a concavity in the top surface of the flexible member. Accordingly, Appellant submits that the disclosure readily allows one of ordinary skill in the art to perceive that the flexible member is "at least in part curved" when in contact with the tissue of the meniscus.

Appellant further submits that the flexible member being at least in part curved when in contact with the tissue is inherently supported in the specification and drawings of Appellant's disclosure as originally filed. According to the MPEP, "[b]y disclosing in a patent application a device that inherently performs a function or has a property, operates according to a theory or has an advantage, a patent application *necessarily* discloses that function, theory or advantage, even though it says nothing explicit concerning it." (MPEP § 2163.07(a), page 2100-184, col. 1 (May 2004)) (emphasis

added). Accordingly, Appellant submits that the Examiner's objection to the subject matter identified in Ground I, sub-ground A as lacking support has been overcome.

For the foregoing reasons, the Examiner's contention in the November 2004 Advisory Action "that the specification states that the flexible member deforms to the surface of the meniscus at an 'angle of the meniscus' not to the curve of the meniscus" is unfounded. (See November 2004 Advisory Action, page 2).

B. The phrase "said flexible member is deformable to have an at least in part concave shape" applicable to claims 33, 105, 148, 183, 214, and 245.

The remarks under item I(A) of the argument above are incorporated by reference herein. Further, Appellant submits that the disclosure readily allows one of ordinary skill in the art to perceive that the flexible member can have a curved top surface with a shape that is "at least in part concave" when in contact with the tissue of the meniscus.

Appellant further submits that the flexible member being deformable to have an at least in part concave shape when in contact with the tissue is inherently supported in the specification and drawings of Appellant's disclosure as originally filed. Accordingly, Appellant submits that the Examiner's objection to the subject matter identified in Ground I, sub-ground B as lacking support has been overcome.

C. The phrase "said flexible member has a greater surface area to mass ratio than said shaft" applicable to claims 34, 65, 106, 149, 184, 215, and 246.

The flexible member having a greater surface area to mass ratio than that of the shaft is supported in the original disclosure at least, for example, in Fig. 4. (A copy of Fig. 4 is attached hereto as Exhibit B). The figures can provide support for the claimed invention to satisfy the written description requirement of 35 U.S.C. § 112, first paragraph. MPEP § 2163(II)(A)(3)(a) states that "[a]n Appellant may show possession of an invention by disclosure of drawings or structural chemical formulas that are sufficiently detailed to show that Appellant was in possession of the claimed invention as a whole. See, e.g., *Vas-Cath*, [citation omitted], ("drawings alone may provide a 'written description' of an invention as required by sec. 112"); *In re Wolfensperger*, [citation omitted], (the drawings of Appellant's specification provided sufficient written descriptive support for the claim limitation at issue); *Autogiro Co. of America v. United*

States, [citation omitted], ("In those instances where a visual representation can flesh out words, drawings may be used in the same manner with the same limitations as the specification.") (MPEP § 2163(II)(A)(3)(a), page 2100-170, col. 2 to page 2100-171, col. 1 (May 2004)).

As shown in Fig. 4, the flexible member has a greater surface area to mass ratio than the shaft. To facilitate the Examiner's understanding of the difference in the surface area to mass ratios, Appellant measured the dimensions of the rivet in Fig. 4 and used these dimensions to calculate their respective ratios. (See Fig. 4, and calculations on page 2 of Exhibit B). In Fig. 4, the surface area to mass ratio of the flexible member is 0.54. The surface area to mass ratio of the shaft is 0.34. Appellant's calculations show, with mathematical certainty, that the flexible member has a greater surface area to mass ratio than the shaft. Accordingly Appellant submits that the disclosure as originally filed supports the relationship set forth in Ground I, sub-ground C.

D. The phrase "said flexible member has a smaller mass than the mass of said shaft" applicable to claims 35, 66, 107, 150, 185, 216, and 247.

The remarks under item I(C) of the argument above are incorporated by reference herein. Further, the flexible member having a smaller mass than that of the shaft is supported in the original disclosure at least, for example, in Fig. 4. (See Fig. 4, Exhibit B).

As the flexible member and shaft are made of the same material, it is clear from Fig. 4 that the mass of the flexible member is less than the mass of the shaft. (See Fig. 4, Exhibit B). Accordingly, Appellant submits that the disclosure as originally filed supports the relationship set forth in Ground I, sub-ground D.

E. The phrase "at least a second portion of said bottom of said flexible member forms an included angle relative to the mid-longitudinal axis of said shaft that is less than 90 degrees" applicable to claim 145.

Appellant respectfully disagrees with the Examiner's contention that the original disclosure does not support a second portion of the bottom of the flexible member forming an included angle relative to the mid-longitudinal axis of the shaft that is less than 90 degrees. An "included angle" is defined as an angle "between or within" two sides. (Merriam Webster's Collegiate Dictionary, 10th ed., page 588, col. 1 (1999); a

copy of page 588 is attached hereto as Exhibit C). Appellant discloses in Fig. 7 an included angle between the bottom of the flexible member and the mid-longitudinal axis of the shaft that is less than 90 degrees. (See angle A as labeled in Fig. 7, a copy of which is attached hereto as Exhibit D).

Appellant respectfully traverses the Examiner's contention that the claim "positively recites that the flexible member is designed with this angle of less than 90 degrees." (November 2004 Advisory Action, page 2). Claim 145 recites that "at least a second portion of said bottom of said flexible member forms an included angle relative to the mid-longitudinal axis that is less than 90 degrees." (Emphasis added). Appellant respectfully submits that the claim is not limited to a "pre-formed" angle of less than 90 degrees as the Examiner contends, but includes the rivet being deformable to "form" the angle of less than 90 degrees upon insertion into the meniscus. This is clearly supported in Fig. 7. Moreover, the Examiner has agreed that the claimed angle exists "after it [the flexible member] has been deformed during use." (November 2004 Advisory Action, page 2). Accordingly, Appellant submits that the disclosure as originally filed supports the angular relationship set forth in Ground I, sub-ground E.

F. The phrase "at least a first portion of said bottom adjacent to said outer perimeter being at an acute angle relative to the mid-longitudinal axis of said shaft" applicable to independent claims 211 and 293.

The bottom of the flexible member having a first portion adjacent the perimeter being at an acute angle relative to the mid-longitudinal axis of the shaft is supported in the original disclosure at least, for example, in Fig. 7. (See Exhibit D). As shown in Fig. 7, there is an acute angle (angle A in Exhibit D) between a first part of the bottom of the flexible member adjacent the outer perimeter and the mid-longitudinal axis of the shaft. Accordingly, Appellant submits that the disclosure as originally filed supports the angular relationship set forth in Ground I, sub-ground F.

Appellant respectfully traverses the Examiner's contention that the claimed angles "are not properties of the device as made." (November 2004 Advisory Action, page 2). The claimed angles must be a property of the rivet as made, otherwise the rivet would not be able to deform to the angle shown in Fig. 7. Accordingly, Appellant

submits that the disclosure as originally filed supports the angular relationship set forth in Ground I, sub-ground F.

G. The phrase "at least a second portion of said bottom adjacent to said outer perimeter being at an obtuse angle relative to the mid-longitudinal axis of said shaft" applicable to independent claims 211 and 293.

The remarks under item I(F) of the argument above are incorporated by reference herein. Further, the bottom of the flexible member having a second portion adjacent the perimeter being at an obtuse angle relative to the mid-longitudinal axis of the shaft is supported in the original disclosure at least, for example, in Fig. 7. (See Exhibit D). As shown in Fig. 7, there is an obtuse angle (angle B in Exhibit D) between a second part of the bottom of the flexible member adjacent the outer perimeter and the mid-longitudinal axis of the shaft. Accordingly, Appellant submits that the disclosure as originally filed supports the angular relationship set forth in Ground I, sub-ground G.

Appellant submits that the Examiner's objection to the January 2004 Amendment under 35 U.S.C. § 132 has been overcome.

II. Objection to the specification under 35 U.S.C. § 112, first paragraph, as not supporting the invention as now claimed.

Appellant respectfully submits that the objection to the specification under 35 U.S.C. § 112, first paragraph as not supporting the invention as now claimed is overcome in view of Appellant's remarks addressing the objection to the Amendment filed January 7, 2004 under 35 U.S.C. § 132 above, those remarks being incorporated by reference herein. (See items I(A) to I(G) of the argument above).

III. Rejection of claims 29-300 under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not adequately described as set forth in the objection to the specification under Ground I above.

Appellant respectfully submits that the rejection improperly rejects all claims even though many claims do not include the features which the Examiner contends is not supported. In particular, Appellant submits that the features which the Examiner identified as not being adequately supported concern only claims 29-59, 65, 66, 100-143, 145, 148-150, 183-185, 211-241, 245-247, and 293-300. The Examiner has not

provided any rationale as to why claims 60-64, 67-99, 144, 146, 147, 151-182, 186-210, 242-244, and 248-292 are rejected under 35 U.S.C. § 112, first paragraph. Accordingly, Appellant submits that these claims are allowable despite the Examiner's blanket rejection of all claims. The Examiner's rejection as it concerns claims 29-59, 65, 66, 100-143, 145, 148-150, 183-185, 211-241, 245-247, and 293-300 is addressed below.

A. Claims 29-59 and 100-143 concerning the phrase "said flexible member being at least in part curved" as recited in independent claims 29 and 100.

Appellant discloses that the flexible member is flexible "so as to be able to conform to the angle of the meniscus M," and "deform so as to conform to the surface of the meniscus." (Specification, page 6, lines 31-33; and page 7, lines 30-31). It is well known to those skilled in the art of orthopedic surgery that the surface of the meniscus is curved. (See, e.g., Anatomy of the Human Body, Gray Henry, 20th ed., Fig. 349 (1918), a copy of which is attached hereto as Exhibit A). The surgeon installs the rivet of the present invention by inserting the shaft into the tissue of the torn meniscus. After the rivet is fully deployed, the shaft will have penetrated the portions of the meniscus tissue being repaired and the flexible member will be in contact with surface of meniscus. When the flexible member contacts the surface of the meniscus, due to the curvature of the meniscus, the forces between the underside of the flexible member and the tissue of the meniscus cause at least a portion of the perimeter of the flexible member to flex away from the shaft. As a result, at least a portion of the perimeter is elevated relative to the middle of the flexible member overlying the shaft, which is held in place by the shaft. This deformation of the flexible member forms a curve to conform to the curve of the top surface of the meniscus into which the flexible member is inserted. As a result of the deformation, the top surface of the flexible member can become curved to create a concavity in the top surface of the flexible member. Accordingly, Appellant submits that the disclosure readily allows one of ordinary skill in the art to perceive that the flexible member is "at least in part curved" when in contact with the tissue of the meniscus.

Appellant further submits that the flexible member being at least in part curved when in contact with the tissue is inherently supported in the specification and drawings

of Appellant's disclosure as originally filed. According to the MPEP, "[b]y disclosing in a patent application a device that inherently performs a function or has a property, operates according to a theory or has an advantage, a patent application *necessarily* discloses that function, theory or advantage, even though it says nothing explicit concerning it." (MPEP § 2163.07(a), page 2100-184, col. 1 (May 2004)) (emphasis added). Accordingly, Appellant submits that the Examiner's objection to the subject matter identified in Ground III, sub-ground A as lacking support has been overcome.

B. Claims 33, 105, 148, 183, 214, and 245 concerning the phrase "said flexible member is deformable to have an at least in part concave shape."

The remarks under item III(A) of the argument are incorporated by reference herein. Further, as a result of the deformation of the flexible member against the surface of the meniscus, the top surface of the flexible member becomes curved to create a concavity in the top surface of the flexible member. Accordingly, Appellant submits that the disclosure readily allows one of ordinary skill in the art to perceive that the flexible member has a top surface with a shape that is "at least in part concave" when in contact with the tissue of the meniscus.

Appellant further submits that the flexible member being deformable to have an at least in part concave shape when in contact with the tissue is inherently supported in the specification and drawings of Appellant's disclosure as originally filed. Accordingly, Appellant submits that the Examiner's objection to the subject matter identified in Ground III, sub-ground B as lacking support has been overcome.

C. Claims 34, 65, 106, 149, 184, 215, and 246 concerning the phrase "said flexible member has a greater surface area to mass ratio than said shaft."

The flexible member having a greater surface area to mass ratio than that of the shaft is supported in the original disclosure at least, for example, in Fig. 4. (See Fig. 4, Exhibit B). The figures can provide support for the claimed invention to satisfy the written description requirement of 35 U.S.C. § 112, first paragraph. MPEP § 2163(II)(A)(3)(a) states that "[a]n Appellant may show possession of an invention by disclosure of drawings or structural chemical formulas that are sufficiently detailed to show that Appellant was in possession of the claimed invention as a whole. See, e.g., *Vas-Cath*, [citation omitted], ("drawings alone may provide a 'written description' of an

invention as required by sec. 112"); *In re Wolfensperger*, [citation omitted], (the drawings of Appellant's specification provided sufficient written descriptive support for the claim limitation at issue); *Autogiro Co of America v. United States*, [citation omitted], ("In those instances where a visual representation can flesh out words, drawings may be used in the same manner with the same limitations as the specification.") (MPEP § 2163(II)(A)(3)(a), page 2100-170, col. 2 to page 2100-171, col. 1 (May 2004)).

As shown in Fig. 4, the flexible member has a greater surface area to mass ratio than the shaft. To facilitate the Board's understanding of the difference in the surface area to mass ratios, Appellant measured the dimensions of the rivet in Fig. 4 and used these dimensions to calculate their respective ratios. (See Fig. 4, and calculations on page 2 of Exhibit B). In Fig. 4, the surface area to mass ratio of the flexible member is 0.54. The surface area to mass ratio of the shaft is 0.34. Appellant's calculations show, with mathematical certainty, that the flexible member has a greater surface area to mass ratio than the shaft. Accordingly, Appellant submits that the disclosure as originally filed supports the relationship set forth in Ground III, sub-ground C.

D. Claims 35, 66, 107, 150, 185, 216, and 247 concerning the phrase "said flexible member has a smaller mass than the mass of said shaft."

The remarks under item III(C) of the argument are incorporated by reference herein. Further, as the flexible member and shaft are made of the same material, it is clear from Fig. 4 that the mass of the flexible member is less than the mass of the shaft. (See Fig. 4, Exhibit B). Accordingly, Appellant submits that the disclosure as originally filed supports the relationship set forth in Ground III, sub-ground D.

E. Claim 145 concerning the phrase "at least a second portion of said bottom of said flexible member forms an included angle relative to the mid-longitudinal axis of said shaft that is less than 90 degrees."

Appellant respectfully disagrees with the Examiner's contention that the original disclosure does not support a second portion of the bottom of the flexible member forming an included angle relative to the mid-longitudinal axis of the shaft that is less than 90 degrees. An "included angle" is defined as an angle "between or within" two sides. (Merriam Webster's Collegiate Dictionary, 10th ed., page 588, col. 1 (1999); Exhibit C). Appellant discloses in Fig. 7 an included angle between the bottom of the

flexible member and the mid-longitudinal axis of the shaft that is less than 90 degrees. (See angle A as labeled in Fig. 7, Exhibit D). Accordingly, Appellant submits that the disclosure as originally filed supports the angular relationship set forth in Ground III, sub-ground E.

F. Claims 211-241 and 293-300 concerning the phrase "at least a first portion of said bottom adjacent to said outer perimeter being at an acute angle relative to the mid-longitudinal axis of said shaft" as recited in independent claims 211 and 293.

The bottom of the flexible member having a first portion adjacent the perimeter being at an acute angle relative to the mid-longitudinal axis of the shaft is supported in the original disclosure at least, for example, in Fig. 7. (See Exhibit D). As shown in Fig. 7, there is an acute angle (angle A in Exhibit D) between a first part of the bottom of the flexible member adjacent the outer perimeter and the mid-longitudinal axis of the shaft. Accordingly, Appellant submits that the disclosure as originally filed supports the angular relationship set forth in Ground III, sub-ground F.

G. Claims 211-241 and 293-300 concerning the phrase "at least a second portion of said bottom adjacent to said outer perimeter being at an obtuse angle relative to the mid-longitudinal axis" as recited in independent claims 211 and 293.

The bottom of the flexible member having a second portion adjacent the perimeter being at an obtuse angle relative to the mid-longitudinal axis of the shaft is supported in the original disclosure at least, for example, in Fig. 7. (See Exhibit D). As shown in Fig. 7, there is an obtuse angle (angle B in Exhibit D) between a second part of the bottom of the flexible member adjacent the outer perimeter and the mid-longitudinal axis of the shaft. Accordingly, Appellant submits that the disclosure as originally filed supports the angular relationship set forth in Ground III, sub-ground G.

Appellant submits that the Examiner's rejection of claims 29-300 under 35 U.S.C. § 112, first paragraph for failing to provide support for the invention as now claimed has been overcome.

IV. Rejection of claims 29-300 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Appellant regards as the invention.

Appellant respectfully submits that this rejection is improper because the Examiner's rationale for supporting the rejection relates to issues of inadequate written support and not to indefiniteness, which is an issue under 35 U.S.C. 112, first paragraph, not second paragraph.

Moreover, Appellant respectfully submits that the Examiner has again improperly rejected all claims when the features identified by the Examiner as allegedly lacking support are not applicable to all claims. In particular, the features identified by the Examiner as allegedly lacking support concern only claims 29-59, 72, 73, 75, 95, 100-143, 145, 148, 156, 158, 173, 183, 191, 193, 208, 211-241, 245, 253, 255, 270, and 293-300 as they existed before the entry of the September 2004 Amendment. The Examiner has not provided any rationale as to why claims 60-71, 74, 76-94, 96-99, 144, 146, 147, 149-155, 157, 159-172, 174-182, 184-190, 192, 194-207, 209, 210, 242-244, 246-252, 254, 256-269, and 271-292 are rejected under 35 U.S.C. § 112, second paragraph. Accordingly, Appellant submits that these claims are allowable despite the Examiner's blanket rejection of all claims. The Examiner's rejection as it concerns claims 29-59, 72, 73, 75, 95, 100-143, 145, 148, 156, 158, 173, 183, 191, 193, 208, 211-241, 245, 253, 255, 270, and 293-300 is addressed below.

A. Claims 40, 41, 72, 73, 114, 115, 156, 191, 222, and 253 concerning the phrase "along the mid-longitudinal axis."

In order to expedite prosecution, Appellant amended claims 40, 41, 72, 73, 114, 115, 156, 191, 222, and 253 in the September 2004 Amendment to change "along" to "around" as indicated by the Examiner as being supported in the disclosure as originally filed. (See March 2004 Office Action, page 3, last full paragraph). The amendment was entered by the Examiner. (November 2004 Advisory Action). The claims now recite that the projections are oriented in arrays "around the mid-longitudinal axis of said shaft." Accordingly, Appellant submits that the rejection of claims 40, 41, 72, 73, 114, 115, 156, 191, 222, and 253 has been overcome.

B. Claims 43, 75, 117, 158, 193, 224, and 255 concerning the phrase "at least two of said projections extend from said shaft in a same plane transverse to the mid-longitudinal axis of said shaft."

Appellant respectfully disagrees with the Examiner's contention that the original disclosure does not support at least two flexible projections extending from the shaft in the same plane transverse to the mid-longitudinal axis of the shaft Appellant discloses at least two flexible projections *extending* from the shaft in the same plane in Fig. 1. A copy of Fig. 1 is attached hereto as Exhibit E with a transverse plane drawn thereon showing two of the flexible projections extending from the shaft along a plane "P."

Moreover, Appellant notes that the Examiner's position in the March 2004 Office Action is inconsistent with the Examiner's earlier position stated in the Office Action dated July 7, 2003. In that Office Action, the Examiner stated that "[i]t would appear in all of the drawings the projections all extend in the same perpendicular plane. Therefore there are always four projections in a plane perpendicular to the longitudinal axis." (Office Action dated July 7, 2003, page 4, paragraph 2). Appellant submits that the disclosure as originally filed supports at least two of the flexible projections extending from the shaft in the same plane transverse to the mid-longitudinal axis of the shaft. Accordingly, Appellant submits that the rejection of claims 43, 75, 117, 158, 193, 224, and 255 has been overcome.

C. Claims 56, 95, 139, 173, 208, 239, and 270 concerning the rivet being approximately 10 mm in length.

In order to expedite prosecution, Appellant amended claims 56, 95, 139, 173, 208, 239, and 270 in the September 2004 Amendment to change "10 mm" to "8 mm," which is supported in the specification on page 8, line 4. The amendment was entered by the Examiner. (November 2004 Advisory Action). Accordingly, Appellant submits that the rejection of claims 56, 95, 139, 173, 208, 239, and 270 has been overcome.

D. Claims 29-59 and 100-143 concerning the flexible member being at least in part curved (recited in independent claims 29 and 100); claims 33, 105, 148, 183, 214, and 245 concerning the flexible member being at least in part concave; and claims 145, 211-241, and 293-300 concerning the member being at an angle not perpendicular to the mid-longitudinal axis.

Appellant submits that the rejection of claims 29-59, 100-143, 145, 148, 183, 211-241, 245, and 293-300 are overcome based on Appellant's remarks addressing the

Examiner's rejection of these claims under 35 U.S.C. § 112, first paragraph above, these remarks being incorporated by reference herein. (See items III(A), III(B), III(E), III(F), and III(G) of the argument above).

Appellant submits that the rejection of claims 29-300 under 35 U.S.C. § 112, second paragraph, as being indefinite has been overcome.

V. The rejection of claims 29-37, 44-52, 60-69, 76-86, 95-111, 114, 115, 118-130, 139-153, 156, 159-167, 173-188, 191, 192, 194-202, 208-219, 222, 225-233, 239-250, 253, 256-264, 270-276, 278, 279, 282-285, 289, 292-294, 296, 297, and 300 under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 5,261,914 to Warren ("Warren").

A. Arguments applicable to all claims under the current rejection: the Examiner's rationale for supporting the rejection in view of Warren is inconsistent with the teachings of Warren.

1. The structure of the head taught by Warren cannot be ignored.

The Examiner states that "[d]ue to the fact that the rivet of Warren is made of the same material as the instant invention and that this material has to be resilient in order to perform, it would appear that [the] rivet of Warren would comprehend the claimed resilient characteristic at least to some extent." (March 2004 Office Action, paragraph bridging pages 4 and 5). By focusing only on the material of the Warren fastener, the Examiner is ignoring the structure of the fastener taught by Warren. Warren teaches that head 110 has a thickness greater than the wall thickness of the shank. (See Warren, col. 3, lines 38-40, 46, and 47; col. 4, lines 66-67). The thickness of the shank wall is obtained by subtracting the rib diameter, 0.157 inches, from the diameter of the internal bore, 0.048 inches, and then dividing the result by two to arrive at 0.0545 inches, which is less than the 0.069 inch thickness of the head. If the head of the Warren fastener were flexible enough to deform to conform to the surface of the tissue as recited, for example, in claims 29 and 60, then shank of the Warren fastener would have insufficient rigidity to withstand repeated blows to be driven into the bone. This result follows because the head has a thickness greater than the wall of the shank. (See, e.g., Warren, Fig. 1). Thus, if the head were modified to be sufficiently flexible as recited in claims 29 and 60, then the shank would be even more flexible because it is thinner than the head. This, of course, ignores any effect of fillet 161, which as

discussed above would operate to inhibit flexibility. Modifying the head of the Warren fastener as suggested by the Examiner would render the shank of the Warren fastener unsatisfactory for its purpose of being able to be driven into bone or bone-like structures. (See MPEP § 2143.01, "The Proposed Modification Cannot Render the Prior Art Unsatisfactory For its Intended Purpose," page 2100-129, col. 2 (May 2004)).

2. The context in which the Warren fastener is used must be considered.

Warren teaches that head 110 is repeatedly struck in order to drive fastener 100 through the tissue and into the bone. (Warren, col. 5, lines 8-16; and Figs. 6-8). The Examiner states that "[t]he only difference between the claims and Warren's device is that the claims recite that the flexible head member deforms when it is pounded into place: Inherently any head member made of a polymeric material when pounded into place on a surface that is curved or irregular will deform at least to a certain extent." (March 2004 Office Action, page 5, paragraph bridging pages 4 and 5). First, Appellant's claims do not recite that the flexible member is "pounded into place." Second, assuming *arguendo* that there were any deformation of the head of Warren during insertion, such deformation would be due to the repeated striking of the head to pound the fastener into the bone, not due to the resilient nature of the flexible member conforming to the surface of tissue.

The Examiner further states that "[b]ecause different portions of the head will come into contact with the bone at different times the head will deform as one portion of the head cannot move and other portions continue to move closer to the bone." (March 2004 Office Action, page 5, paragraph bridging pages 4 and 5). Appellant respectfully submits that the Examiner is ignoring the context in which Warren teaches using the fastener. Warren teaches driving the fastener through ligament 200 and into bone 300. (Warren, col. 5, lines 13-14; Figs. 7 and 8). As the fastener is pounded into the bone, the head "captivates the ligament against the bone." (Warren, col. 5, lines 15-16). The head taught by Warren is not designed to be used against bone, but rather "ligaments or ligament-like objects." (Warren, col. 7, lines 28-29). As the head of the Warren fastener is pounded in, it will contact the softer ligament. Thus, any deformation as between the head and the ligament will be confined to the ligament deforming, not the

head. To attempt to use the fastener of Warren to attach only bone segments together would change the principal operation of the Warren fastener. The Examiner's modification of the principal of operation of the Warren fastener is not permissible. (See MPEP § 2143.01, "The Proposed Modification Cannot Change the Principle of Operation of a Reference," page 2100-132, col. 1 (May 2004)).

3. The Examiner's redesign of the Warren fastener is without teaching or suggestion.

The Examiner states that "Warren teaches that the fastener can be thinner." (March 2004 Office Action, page 5, paragraph bridging pages 5 and 6). The Examiner then redesigns the Warren fastener to fit within the scope of Appellant's claimed invention. (See March 2004 Office Action, paragraph bridging pages 5 and 6). The Examiner states that a thinner fastener "would then result in a head member that would flex as it is forced into contact with the bone," and that finding the right dimensions "would result in a head that flexes during implantation." (March 2004 Office Action, paragraph bridging pages 5 and 6). Appellant respectfully submits that the Examiner's redesign of the Warren fastener is improper. First, the Examiner has not provided any motivation as to why one would modify the Warren fastener to have "a head that flexes." (March 2004 Office Action, page 6, paragraph bridging pages 5 and 6) (See MPEP § 2143.01, "the Prior Art Must Suggest the Desirability of the Claimed Invention," page 2100-129, col. 2 (May 2004)). Second, modifying the Warren fastener as suggested by the Examiner render it unsuitable for its intended purpose of being able to be pounded into bone as taught by Warren. (See MPEP § 2143.01, "The Proposed Modification Cannot Render the Prior Art Unsatisfactory For its Intended Purpose," page 2100-131, col. 2 (May 2004)). Accordingly, the Examiner's proposed redesign of the Warren fastener cannot be applied in the rejection.

4. The Examiner is using impermissible hindsight.

Appellant also submits that the Examiner is using impermissible hindsight in order to fashion a motivation to support the rejection. The Examiner states that "it would have been obvious to modify the rivet of Warren" to have "a head that flexes." (March 2004 Office Action, page 6, paragraph bridging pages 5 and 6). Such a motivation is not suggested in the art cited by the Examiner. In the specification,

Appellant teaches a flexible member that is "sufficiently flexible so as to be able to conform to the angle of the meniscus." (Specification, page 6, lines 31-33). Appellant submits that prior to Appellant's teachings, there was no motivation to have a head that flexes.

It is respectfully submitted that the Examiner is using impermissible hindsight by gleaning the motivation used to reject the present claims over Warren from Appellant's own teachings in the specification. (See MPEP § 2141.01(III), page 2100-121, col. 2 (May 2004) ("[i]t is difficult but necessary that the decision-maker forget what he or she has been taught...about the claimed invention and cast the mind back to the time the invention was made (often as here many years), to occupy the mind of one skilled in the art who is presented only with the references, and who is normally guided by the then-accepted wisdom in the art." (citation omitted)). Appellant respectfully submits that the rejection was not framed with the mind of one skilled in the art presented only with the references and then-commonly accepted wisdom in the art, but with the guidance of Appellant's teachings. It is therefore submitted that a *prima facie* case of obviousness has not been established.

B. Arguments applicable to separately grouped claims.

1. Claims 29-31, 33-37, and 44-52.

Warren teaches away from the claimed invention. Warren discloses a surgical fastener for attaching soft tissues to bone or bone-like structures. (Warren, col. 7, lines 22-31). In order to insert the fastener into the bone, Warren teaches that head 110 is repeatedly struck in order to drive fastener 100 through the tissue and into the bone. (Warren, col. 5, lines 8-16; and Figs. 6-8). Accordingly, the structure of head 110 must be able to withstand repeated blows to drive the fastener into bone.

Warren discloses two ways that the head is made sufficiently rigid to withstand pounding. First, head 110 is made thick. Warren teaches that the thickness of head 110 is 0.069 inches, which is more thick than any part of the shank wall 115 perpendicular to the longitudinal axis of the fastener. (Warren, col. 3, lines 38-40; Fig. 1). Secondly, Warren teaches the use of a fillet 161 at the junction of shank portion 115 and lower surface 160 of head 110. (Warren, col. 3, lines 40-42). As is

known in the art, fillets are used to reinforce a corner where two surfaces meet. (See, e.g., Merriam Webster's Collegiate Dictionary, 10th ed., page 435, col. 1 (1999); a copy of page 435 is attached hereto as Exhibit F). Accordingly, the head of the Warren fastener is rigid in order to withstand repeated pounding so that the fastener can be driven into bone.

Independent claim 29 recites a tissue rivet having a flexible member at the trailing end, the flexible member being adapted to "deform so as to conform to the surface of the tissue in which said rivet is inserted," and being "at least in part curved when said flexible member is in contact with the tissue." As shown in Fig. 8 of Warren, the reinforced head of fastener 100 remains straight when in contact with tissue after insertion. There is no teaching or suggestion in Warren of the flexible member being at least in part curved when in contact with tissue as recited in claim 29.

Not only does Warren not teach or suggest a rivet as recited in claim 29, Warren teaches away from the subject matter of this claim. Warren teaches away from claim 29 by using a head design that must have a sufficient rigidity to withstand repeated blows to drive the fastener into bone. Such a fastener teaches away from Appellant's claimed invention because its head is not flexible as recited in independent claim 29.

2. Claim 32.

Appellant further submits that the cited art, whether alone or in proper combination, fails to teach or suggest the subject matter of claim 32. Claim 32 recites the flexible member having an outer edge that is beveled. In the March 2004 Office Action, the Examiner contends that "making the head of the fastener less obtrusive so that it is flush with the bone surface so that the skin does not rub against the head is a well-recognized problem in the art." (March 2004 Office Action, page 6, paragraph 1).

Pursuant to MPEP 2144.03(c), Appellant challenged the Examiner's assertion that the skin rubbing over the head of a tissue fastener is a well-recognized problem in the art that is solved by making the heads flush. (See MPEP 2144.03(c), "[i]f Appellant challenges a factual assertion as not properly Officially Noticed or not properly based upon common knowledge, the Examiner must support the finding with adequate evidence," page 2100-138, col. 1 (May 2004)). First, the skin of a patient makes no contact with a trailing end of a rivet that is inserted into the meniscus of the knee. The

flexible member of the rivet taught by Appellant is configured to minimize interference with normal knee-joint motion, not skin abrasion. Second, none of the analogous art cited by the Examiner teach or suggest, whether alone or in proper combination, a flexible member having a beveled outer edge. (See, e.g., Bays, Fig. 3; Warren, Fig. 8; and Duncan, Fig. 9). Also, according to the MPEP, "[i]f the examiner is relying on personal knowledge to support the finding of what is known in the art, the examiner must provide an affidavit or declaration setting forth specific factual statements and explanation to support the finding. See 37 CFR 1.104(d)(2)." (MPEP 2144.03(c), page 2100-138, col. 1 (May 2004)).

In the November 2004 Advisory Action, the Examiner failed to provide the evidence requested by Appellant in accordance with MPEP § 2144.03(c). Accordingly, Appellant submits that the rejection of claim 32 should be withdrawn.

3. Claims 60-63, 65-69, 76-86, and 95-99.

Independent claim 60 recites the flexible member being adapted to "deform so as to conform to the surface of the tissue in which said rivet is inserted," and the top of the flexible member being "at least in part concave when said flexible member is in contact with the tissue." As shown in Fig. 8 of Warren, the reinforced head of fastener 100 remains straight when in contact with tissue after insertion. There is no teaching or suggestion in Warren of the flexible member being at least in part concave as recited in claim 60.

Not only does Warren not teach or suggest a rivet as recited in claim 60, Warren teaches away from the subject matter of this claim. Warren teaches away from claim 60 by using a head design that must have a sufficient rigidity to withstand repeated blows to drive the fastener into bone. Such a fastener teaches away from Appellant's claimed invention because its head is not flexible as recited in independent claim 60.

4. Claim 64.

Claim 64 recites the flexible member having an outer edge that is beveled. In the March 2004 Office Action, the Examiner contended that "making the head of the fastener less obtrusive so that it is flush with the bone surface so that the skin does not rub against the head is a well-recognized problem in the art." (March 2004 Office Action, page 6, paragraph 1).

In accordance with MPEP 2144.03(c), Appellant challenged the Examiner's assertion. (See remarks concerning claim 32 above (item V(B)(2) of the argument), which are incorporated by reference herein). In the November 2004 Advisory Action, the Examiner failed to provide the evidence requested by Appellant in accordance with MPEP § 2144.03(c). Accordingly, Appellant submits that the rejection of claim 64 should be withdrawn.

5. Claims 100-103, 105-111, 114, 115, 118-130, and 139-143.

Independent claim 100 recites the flexible member being "at least in part curved when said bottom of said flexible member contacts the tissue." As shown in Fig. 8 of Warren, the reinforced head of fastener 100 remains straight when in contact with tissue after insertion. There is no teaching or suggestion in Warren of the flexible member being at least in part curved when in contact with tissue as recited in claim 100.

Not only does Warren not teach or suggest a rivet as recited in claim 100, Warren teaches away from the subject matter of this claim. Warren teaches away from claim 100 by using a head design that must have a sufficient rigidity to withstand repeated blows to drive the fastener into bone. Such a fastener teaches away from Appellant's claimed invention because its head is not flexible as recited in independent claim 100.

6. Claim 104.

Claim 104 recites the flexible member having an outer edge that is beveled. In the March 2004 Office Action, the Examiner contended that "making the head of the fastener less obtrusive so that it is flush with the bone surface so that the skin does not rub against the head is a well-recognized problem in the art." (March 2004 Office Action, page 6, paragraph 1).

In accordance with MPEP 2144.03(c), Appellant challenged the Examiner's assertion. (See remarks concerning claim 32 above (item V(B)(2) of the argument), which are incorporated by reference herein). In the November 2004 Advisory Action, the Examiner failed to provide the evidence requested by Appellant in accordance with MPEP § 2144.03(c). Accordingly, Appellant submits that the rejection of claim 104 should be withdrawn.

7. Claims 144-153, 156, 159-167, and 173-175.

Independent claim 144 recites at least a portion of the bottom of the flexible member "forming an included angle relative to the mid-longitudinal axis of said shaft that is greater than 90 degrees." Warren teaches a fastener with a head having a bottom that is perpendicular to the mid-longitudinal axis of the shank. (See Warren, Fig. 8). Warren does not teach or suggest a tissue rivet having the angular relationship as recited in independent claim 144.

Not only does Warren not teach or suggest a rivet as recited in claim 144, Warren teaches away from the subject matter of this claim. Warren teaches away from claim 144 by using a head design that must have a sufficient rigidity to withstand repeated blows to drive the fastener into bone. Such a fastener teaches away from Appellant's claimed invention because its head is not flexible as recited in independent claim 144.

8. Claims 176-188, 191, 194-202, and 208-210.

Independent claim 176 recites the flexible member having an outer perimeter, "at least a portion of said outer perimeter being flexible relative to said shaft when said rivet is inserted into the tissue." The head taught by Warren is not configured for moving or flexing, at least due to the greater thickness of the head relative to the shank, and fillet 161 as discussed above. (See, e.g., Warren, Fig. 1). Warren does not teach or suggest a tissue rivet as recited in independent claim 176.

Not only does Warren not teach or suggest a rivet as recited in claim 176, Warren teaches away from the subject matter of this claim. Warren teaches away from claim 176 by using a head design that must have a sufficient rigidity to withstand repeated blows to drive the fastener into bone. Such a fastener teaches away from Appellant's claimed invention because its head is not flexible as recited in independent claim 176.

9. Claim 192.

Dependent claim 192 recites a plurality of projections "positioned in a radially staggered configuration along said shaft." Warren does not teach or suggest such a configuration. Moreover, the Examiner has failed to provide any grounds and/or motivation for the rejection specific to the subject matter of claim 192. Therefore, it is